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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/887,469	06/22/2001	Christine D. Krempl	NIH-013/E-225-00/1	6953

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Woodcock Washburn LLP
One Liberty Place 46th Floor
Philadelphia, PA 19103

EXAMINER
BROWN, STACY S

ART UNIT	PAPER NUMBER
1648	10

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/887,469	KREMPL ET AL.	
	Examiner	Art Unit	
	Stacy S Brown	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 June 2001* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-207* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-207* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1648.**

2. Claims 1-207 are pending.

Election/Restrictions

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-67, 96-99 and 109-114, drawn to an isolated infectious recombinant RSV having a shifted gene, classified in class 424, subclass 211.1.

- Further restriction is required if Group I is elected. Applicant must elect either human or bovine displacement polynucleotides from claim 6.

II. Claims 68-93 and 115-123, drawn to a chimeric RSV having a shifted gene, classified in class 424, subclass 199.1.

- Further restriction is required if Group II is elected. Applicant must elect one of the following from claim 120: measles, RSV, mumps, HPV, HIV, HSV, CMV, rabies, EBV, filovirus, bunyavirus, flavivirus, alphavirus or influenza.

III. Claims 94-95, drawn to a chimeric RSV/PIV having a shifted gene, classified in class 424, subclass 199.1.

IV. Claims 100-108, drawn to a method for stimulating an immune response, classified in class 435, subclass 5.

V. Claims 124-167, 174 and 185-197, drawn to an RSV polynucleotide having a shifted gene, classified in class 536, subclass 23.72.

VI. Claims 168-173, drawn to a chimeric RSV polynucleotide having a shifted gene, classified in class 536, subclass 23.72.

VII. Claims 175-184, drawn to a RSV polynucleotide having a shifted gene and attenuating mutations, classified in class 536, subclass 23.72.

VIII. Claims 198-199, drawn to a method of producing RSV having a shifted gene, classified in class 435, subclass 69.1.

IX. Claims 200-206, drawn to a human/bovine chimeric RSV, classified in class 424, subclass 199.1.

X. Claim 207, drawn to a human/bovine chimeric RSV polynucleotide, classified in class 536, subclass 23.72.

The inventions are distinct, each from the other because of the following reasons:

a) Inventions I-III, V-VII and IX-X and all are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to different RSVs and polynucleotides encoding them: recombinant and human/bovine chimerics. The viruses and polynucleotides are distinct inventions having different chemical structures and functions. The RSV products are distinct from each other because they have different structures (chimerics) and different modes of operation, function and effect. The recombinant RSV and respective polynucleotides does not share the same functions as

the human/bovine chimeric since they produce different results and immune responses. The recombinant RSV (Group IX) and polynucleotide encoding it (X) are distinct from the other RSVs and polynucleotides because they lack the shifted gene of inventions I-III and V-VII.

b) Inventions I-III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in a materially different process such as an infectivity assay.

c) Inventions I-III and VIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products can be made by another process such as ligation.

d) Inventions IV and (V-VII and IX-X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method for stimulating an immune response and polynucleotides/RSVs. The products and process are not

disclosed as capable of use together and have different modes of operation, function and effect.

e) Inventions IV and VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods of stimulating an immune response and producing an RSV. These methods have different methods steps, modes of operation, function and effect. The methods are not disclosed as capable of use together.

f) Inventions V-VII and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products can be used in a materially different process, such as stimulating an immune response.

g) Inventions VIII and (IX-X) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a method of producing RSV having a shifted gene, and an RSV and corresponding polynucleotide lacking the shifted gene. The method and products are not disclosed as capable of use together.

Because these inventions are distinct for the reasons given above and the search required for one group is neither required nor-coextensive for any other group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday and alternate Wednesdays from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

HANKYEL T. PARK, PH.D
PRIMARY EXAMINER

Stacy S. Brown
July 15, 2002